

I applaud provisions of this bill which seek to educate the public on organ donation. It is by reaching folks one by one that awareness is raised. In New Mexico much of the public has misconceptions about this important issue. Since we have lost our transplant programs, many individuals decide that the travel distance, time, separation from family, and logistics are just too hampering. It is just too complicated and too much of a burden. We have some of the highest rates of Diabetes, Kidney disease, and Hepatitis B and C of any state, and yet our rates of transplants are among the lowest. We need hearts, we need livers, we need pancreases, and we need the ones we procure to stay close to home.

I also reiterate support for the sense of Congress contained in his bill that refers to family discussions of donation. Encouraging such dialogues to take place will help make decisions early. There are 32 states in which being designated an organ donor on a driver's license carries no legal weight at all. It is by communicating an individual's desires with family members that counts. Oftentimes, it is a point of crisis in which a family must make a decision whether or not to donate a loved ones' organs. If this is talked about beforehand, the desires of each family member can be made known. It is families that are affected by organ donation, and families that should make the decisions.

Mr. STARK. Mr. Speaker, I rise in support of the Organ Donation Improvement Act of 2003, H.R. 399. The commendable purpose of this bill is to increase public awareness of the need for organ donation and institute procedures to increase the frequency of this brave and noble act.

There is a serious shortage of available organs for donation. There are currently over 80,000 people waiting for an organ transplant and a new name is added to the waiting list every 13 minutes. As a result of the low rate of organ donation in this country, more than 6,000 people died in 2001 for lack of an available suitable organ. The passage of this bill and the implementation of its provisions will help to markedly reduce the number of such deaths in the future.

I commend Representative MICHAEL BILIRAKIS for introducing this bill and taking interest in this vital area. I encourage my colleagues to support this life saving legislation.

Mr. UPTON. Mr. Speaker, I rise in support of H.R. 399, the Organ Donation Improvement Act of 2003, of which I am a cosponsor. Let me just mention one number, that for me, says it all about why we need incentives to increase organ donations across the nation. In Michigan, over an 11-month period ending on December 1 of last year, 2,420 individuals were waiting for organs, and 164 people had died while waiting. These are our constituents, our families, our friends. I know the Transplant Society of Michigan, our state's organ procurement organization, is working hard to increase donations. But they could use a helping hand, as could OPOs across the nation. The Organ Donation Improvement Act we are marking up today is a very good start.

As of September 2002, the organ transplant waiting list had more than 80,000 men, women, and children waiting for a new kidney, heart, liver, lung, pancreas, or intestine. Unfortunately, an average of 17 people die every day, one every 85 minutes, waiting for an organ that could have saved their lives. H.R.

399 takes aim at increasing anatomical giving to help meet the critical need for vital human organs and give hope for life for those that have no other options for treatment or cure.

The key to donation is public education and awareness. This legislation gives the Secretary of Health and Human Services the ability to award grants to States for the purpose of assisting States in carrying out organ donor awareness, public education and outreach activities designed to increase the number of organ donors. While there is a desperate need for vital human organs, the American public should know that there is also a continuing need for donated human eyes and tissue. Donation is the term used to describe the humanitarian act of giving to help another. Anatomical gifts include vital, life-saving human organs, sight restoring eyes, and repair and reconstruction human tissue such as bone, cartilage, tendons, skin, and heart valves.

At national, state, and local levels, a partnership exists between the organ, eye and tissue bank communities. While all three communities are considered separate, given differences in medical criteria, training needs and distribution pathways, they are united in their message to encourage the act of donation. Organ donation saves lives, eye donation restores sight, and tissue donation provides skin grafts for critically injured burn patients and benefits thousands of patients in need of bone, cartilage, tendons, and heart valves. Without a donor, transplant surgeons cannot save and improve the health of even one individual.

Every individual can sign-up to be a donor, regardless of health or medical condition. It is imperative, however, that individuals openly discuss their decision to donate with family and friends so that they may help honor their loved one's wishes and are knowledgeable about their options. Just one individual can save and improve as many as 50 lives. Representatives of hospitals, organ banks, eye banks, and tissue banks work hand in hand to see that loved ones' wishes are respected and that gifts are properly handled for the benefit of others. I commend these organizations for working tirelessly toward this end and for their efforts to educate the public on the benefits of donation.

In closing, I fully encourage all Americans to consider the altruistic act of donation and to make others aware of your decision.

Ms. BORDALLO. Mr. Speaker, today, I join my colleagues in support of H.R. 399 to amend the Public Health Service Act to promote organ donation. I want to thank Congressman BILIRAKIS for his commitment to this cause.

The advances in technology have increased the chances of survival for many suffering from life-threatening illnesses. But technology alone is not enough. In many cases, survival depends on some form of transplant. Sadly, the need far exceeds the number of donors. H.R. 399 is a big step in addressing this serious demand.

Educating the public about the need for donors and the ways one can become a donor is crucial. Many believe that donation only comes at the end of a life. But each year thousands get a new change at life through the generosity and courage of living donors. For the families facing the loss of a loved one, donation is a legacy of life and an example of the best of humanity in the face of tragedy.

In promoting awareness of the need for donors, H.R. 399 offers hope to thousands waiting for another chance at life. I strongly support H.R. 399 and urge its passage.

Mr. JOHN. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

Mr. SHIMKUS. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Louisiana (Mr. TAUZIN) that the House suspend the rules and pass the bill, H.R. 399.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds of those present have voted in the affirmative.

Mr. SHIMKUS. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX and the Chair's prior announcement, further proceedings on this motion will be postponed.

PATIENT SAFETY AND QUALITY IMPROVEMENT ACT

Mr. BILIRAKIS. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 663) to amend title IX of the Public Health Service Act to provide for the improvement of patient safety and to reduce the incidence of events that adversely affect patient safety, and for other purposes, as amended.

The Clerk read as follows:

H.R. 663

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Patient Safety and Quality Improvement Act".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Findings and purposes.

TITLE I—PATIENT SAFETY AND QUALITY IMPROVEMENT

Sec. 101. Amendments to Public Health Service Act.

"PART C—PATIENT SAFETY IMPROVEMENT"

"Sec. 921. Definitions.

"Sec. 922. Privilege for patient safety work product.

"Sec. 923. National Patient Safety Database.

"Sec. 924. Technical assistance.

"Sec. 925. Certification of patient safety organizations.

Sec. 102. Promoting the diffusion and interoperability of information technology systems involved with health care delivery.

Sec. 103. Required use of product identification technology.

Sec. 104. Grants for electronic prescription programs.

Sec. 105. Grants to hospitals and other health care providers for information technologies.

Sec. 106. Authorization of appropriations for grants under sections 104 and 105.

TITLE II—MEDICAL INFORMATION
TECHNOLOGY ADVISORY BOARD.

Sec. 201. Medical Information Technology
Advisory Board.

SEC. 2. FINDINGS AND PURPOSES.

(a) FINDINGS.—The Congress finds as follows:

(1) In 1999, the Institute of Medicine released a report entitled “To Err Is Human” that described medical errors as the 8th leading cause of death in the United States, with as many as 98,000 people dying as a result of medical errors each year.

(2) To address these deaths and injuries due to medical errors, the health care system must identify and learn from such errors so that systems of care can be improved.

(3) Myriad public and private patient safety initiatives have begun. The Quality Interagency Coordination Task Force has recommended steps to improve patient safety that may be taken by each Federal agency involved in health care and activities relating to these steps are ongoing.

(4) The Department of Health and Human Services has initiated several patient safety projects. The Joint Commission on Accreditation of Healthcare Organizations issued a patient safety standard that went into effect on July 1, 2001, and the peer review organizations are conducting ongoing studies of clinical performance measurement of care delivered to beneficiaries under the medicare program under title XVIII of the Social Security Act.

(5) Several steps can be taken now to improve patient safety. For example, according to the Centers for Disease Control and Prevention, hand washing is the single most important means of preventing the spread of infection. Repeated studies indicate that lack of or improper hand washing still contributes significantly to disease transmission in health care settings. Working with experts from the private sector, the Centers for Disease Control and Prevention has drafted “Guidelines for Hand Hygiene in Healthcare Settings” setting forth recommendations to promote improved hand hygiene practices and reduce transmission of pathogenic microorganisms to patients and personnel in health care settings.

(6) According to the Centers for Disease Control and Prevention, nosocomial infections affect approximately 2 million patients annually in acute care facilities in the United States at an estimated direct patient care cost of approximately \$3.5 billion each year.

(7) The Congress encourages the continuation and acceleration of private sector efforts to take immediate steps to improve patient safety and recognizes the need for action in the public sector to complement these efforts.

(8) The research on patient safety unequivocally calls for a learning environment, where providers will feel safe to report health care errors, in order to improve patient safety.

(9) Voluntary data gathering systems are more supportive than mandatory systems in creating the learning environment referred to in paragraph (8) as stated in the Institute of Medicine’s report.

(10) Promising patient safety reporting systems have been established throughout the United States, and the best ways to structure and use these systems are currently being determined, largely through projects funded by the Agency for Healthcare Research and Quality.

(11) Many organizations currently collecting patient safety information have expressed a need for protections that will allow them to review protected information so that they may collaborate in the develop-

ment and implementation of patient safety improvement strategies. Currently, the State peer review protections provide inadequate conditions to allow the sharing of information to promote patient safety.

(12) In 2001, the Institute of Medicine released a report entitled “Crossing the Quality Chasm” that found that the United States health care system does not consistently deliver high-quality care to patients.

(b) PURPOSES.—The purposes of this Act are—

(1) to encourage a culture of safety and quality in the United States health care system by providing for a health care errors reporting system that both protects information and improves patient safety and quality of health care; and

(2) to ensure accountability by raising standards and expectations for continuous quality improvements in patient safety through the actions of the Secretary of Health and Human Services.

**TITLE I—PATIENT SAFETY AND QUALITY
IMPROVEMENT**

**SEC. 101. AMENDMENTS TO PUBLIC HEALTH
SERVICE ACT.**

(a) IN GENERAL.—Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) is amended—

(1) in section 912(c), by inserting “, in accordance with part C,” after “The Director shall”;

(2) by redesignating part C as part D;

(3) by redesignating sections 921 through 928, as sections 931 through 938, respectively;

(4) in section 938(1) (as so redesignated), by striking “921” and inserting “931”; and

(5) by inserting after part B the following:

**“PART C—PATIENT SAFETY
IMPROVEMENT**

“SEC. 921. DEFINITIONS.

“In this part:

“(1) IDENTIFIABLE INFORMATION.—The term ‘identifiable information’ means information that is presented in a form and manner that allows the identification of any provider, patient, or reporter of patient safety work product. With respect to patients, such information includes any individually identifiable health information as that term is defined in the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191; 110 Stat. 2033).

“(2) NONIDENTIFIABLE INFORMATION.—The term ‘nonidentifiable information’ means information that is presented in a form and manner that prevents the identification of any provider, patient, or reporter of patient safety work product. With respect to patients, such information must be de-identified consistent with the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191; 110 Stat. 2033).

“(3) PATIENT SAFETY EVALUATION SYSTEM.—The term ‘patient safety evaluation system’ means a process that involves the collection, management, or analysis of information for submission to or by a patient safety organization.

“(4) PATIENT SAFETY ORGANIZATION.—The term ‘patient safety organization’ means a private or public organization or component thereof that is certified, through a process to be determined by the Secretary under section 925, to perform each of the following activities:

“(A) The conduct, as the organization or component’s primary activity, of efforts to improve patient safety and the quality of health care delivery.

“(B) The collection and analysis of patient safety work product that is submitted by providers.

“(C) The development and dissemination of evidence-based information to providers with respect to improving patient safety, such as recommendations, protocols, or information regarding best practices.

“(D) The utilization of patient safety work product to carry out activities limited to those described under this paragraph and for the purposes of encouraging a culture of safety and of providing direct feedback and assistance to providers to effectively minimize patient risk.

“(E) The maintenance of confidentiality with respect to identifiable information.

“(F) The provision of appropriate security measures with respect to patient safety work product.

“(G) The submission of nonidentifiable information to the Agency consistent with standards established by the Secretary under section 923(b) for any National Patient Safety Database.

“(5) PATIENT SAFETY WORK PRODUCT.—

“(A) The term ‘patient safety work product’ means any document or communication (including any information, report, record, memorandum, analysis, deliberative work, statement, or root cause analysis) that—

“(i) except as provided in subparagraph (B), is developed by a provider for the purpose of reporting to a patient safety organization, and is reported to a patient safety organization;

“(ii) is created by a patient safety organization; or

“(iii) would reveal the deliberations or analytic process of a patient safety evaluation system (as defined in paragraph (3)).

“(B)(i) Patient safety work product described in subparagraph (A)(i)—

“(I) does not include any separate information described in clause (i); and

“(II) shall not be construed to include such separate information merely by reason of inclusion of a copy of the document or communication involved in a submission to, or the fact of submission of such a copy to, a patient safety organization.

“(ii) Separate information described in this clause is a document or communication (including a patient’s medical record or any other patient or hospital record) that is developed or maintained, or exists, separately from any patient safety evaluation system.

“(C) Information available from sources other than a patient safety work product under this section may be discovered or admitted in a civil or administrative proceeding, if discoverable or admissible under applicable law.

“(6) PROVIDER.—The term ‘provider’ means—

“(A) an individual or entity licensed or otherwise authorized under State law to provide health care services, including—

“(i) a hospital, nursing facility, comprehensive outpatient rehabilitation facility, home health agency, and hospice program;

“(ii) a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified nurse midwife, nurse anesthetist, psychologist, certified social worker, registered dietitian or nutrition professional, physical or occupational therapist, or other individual health care practitioner;

“(iii) a pharmacist; and

“(iv) a renal dialysis facility, ambulatory surgical center, pharmacy, physician or health care practitioner’s office, long-term care facility, behavioral health residential treatment facility, clinical laboratory, or community health center; or

“(B) any other person or entity specified in regulations by the Secretary after public notice and comment.

"SEC. 922. PRIVILEGE FOR PATIENT SAFETY WORK PRODUCT.

"(a) PRIVILEGE.—Notwithstanding any other provision of law and subject to subsection (c), patient safety work product shall not be—

"(1) subject to a civil or administrative subpoena or order;

"(2) subject to discovery in connection with a civil or administrative proceeding;

"(3) subject to disclosure pursuant to section 552 of title 5, United States Code (commonly known as the Freedom of Information Act), or any other similar Federal or State law;

"(4) required to be admitted as evidence or otherwise disclosed in any State or Federal civil or administrative proceeding; or

"(5) if the patient safety work product is identifiable information and is received by a national accreditation organization in its capacity as a patient safety organization—

"(A) used by a national accreditation organization in an accreditation action against the provider that reported the information;

"(B) shared by such organization with its survey team; or

"(C) required as a condition of accreditation by a national accreditation association.

"(b) REPORTER PROTECTION.—

"(1) IN GENERAL.—A provider may not use against an individual in an adverse employment action described in paragraph (2) the fact that the individual in good faith reported information—

"(A) to the provider with the intention of having the information reported to a patient safety organization; or

"(B) directly to a patient safety organization.

"(2) ADVERSE EMPLOYMENT ACTION.—For purposes of this subsection, an 'adverse employment action' includes—

"(A) the failure to promote an individual or provide any other employment-related benefit for which the individual would otherwise be eligible;

"(B) an adverse evaluation or decision made in relation to accreditation, certification, credentialing, or licensing of the individual; and

"(C) a personnel action that is adverse to the individual concerned.

"(3) REMEDIES.—Any provider that violates this subsection shall be subject to a civil monetary penalty of not more than \$20,000 for each such violation involved. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A of the Social Security Act are imposed and collected.

"(c) DISCLOSURES.—Nothing in this section prohibits any of the following disclosures:

"(1) Voluntary disclosure of nonidentifiable information.

"(2) Voluntary disclosure of identifiable information by a provider or patient safety organization, if such disclosure—

"(A) is authorized by the provider for the purposes of improving quality and safety;

"(B) is to an entity or person subject to the requirements of section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191; 110 Stat. 2033), or any regulation promulgated under such section; and

"(C) is not in conflict with such section or any regulation promulgated under such section.

"(3) Disclosure as required by law by a provider to the Food and Drug Administration, or on a voluntary basis by a provider to a federally established patient safety program, with respect to an Administration-regulated product or activity for which that entity has responsibility, for the purposes of activities related to the quality, safety, or effective-

ness of such Administration-regulated product or activity.

"(4) Disclosures of patient safety work product in accordance with this part by a provider to a patient safety organization.

"(d) EFFECT OF TRANSFER, DISCLOSURE.—The following shall not be treated as a waiver of any privilege or protection established under this part:

"(1) The transfer of any patient safety work product between a provider and a patient safety organization.

"(2) Disclosure of patient safety work product as described in subsection (c).

"(3) The unauthorized disclosure of patient safety work product.

"(e) PENALTY.—

"(1) PROHIBITION.—Except as provided in this part, and subject to paragraphs (2) and (4), it shall be unlawful for any person to disclose patient safety work product in violation of this section, if such disclosure constitutes a negligent or knowing breach of confidentiality.

"(2) RELATION TO HIPAA.—The penalty under paragraph (3) for a disclosure in violation of paragraph (1) does not apply if the person would be subject to a penalty under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191; 110 Stat. 2033), or any regulation promulgated under such section, for the same disclosure.

"(3) AMOUNT.—Any person who violates paragraph (1) shall be subject to a civil monetary penalty of not more than \$10,000 for each such violation involved. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A of the Social Security Act are imposed and collected.

"(4) SUBSEQUENT DISCLOSURE.—Paragraph (1) applies only to the first person that breaches confidentiality with respect to particular patient safety work product.

"(f) RELATION TO HIPAA.—

"(1) IN GENERAL.—For purposes of applying the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191; 110 Stat. 2033)—

"(A) patient safety organizations shall be treated as business associates; and

"(B) activities of such organizations described in section 921(4) in relation to a provider are deemed to be health care operations (as defined in such regulations) of the provider.

"(2) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to alter or affect the implementation of such regulations or such section 264(c).

"(g) NO LIMITATION OF OTHER PRIVILEGES.—Nothing in this section shall be construed to affect privileges, including peer review and confidentiality protections, that are otherwise available under Federal or State laws.

"(h) NO LIMITATION ON CONTRACTS.—Nothing in this section shall be construed to limit the power of a provider and a patient safety organization, or a patient safety organization and the Agency or any National Patient Safety Database, consistent with the provisions of this Act and other applicable law, to enter into a contract requiring greater confidentiality or delegating authority to make an authorized disclosure.

"(i) RELATION TO STATE REPORTING REQUIREMENTS.—Nothing in this part shall be construed as preempting or otherwise affecting any State law requiring a provider to report information, including information described in section 921(5)(B), that is not patient safety work product.

"(j) CONTINUATION OF PRIVILEGE.—Patient safety work product of an organization that is certified as a patient safety organization shall continue to be privileged and confiden-

tial, in accordance with this section, if the organization's certification is terminated or revoked or if the organization otherwise ceases to qualify as a patient safety organization.

"(k) REPORTS ON STRATEGIES TO IMPROVE PATIENT SAFETY.—

"(1) DRAFT REPORT.—Not later than the date that is 18 months after any National Patient Safety Database is operational, the Secretary, in consultation with the Director, shall prepare a draft report on effective strategies for reducing medical errors and increasing patient safety. The draft report shall include any measure determined appropriate by the Secretary to encourage the appropriate use of such strategies, including use in any federally funded programs. The Secretary shall make the draft report available for public comment and submit the draft report to the Institute of Medicine for review.

"(2) FINAL REPORT.—Not later than 1 year after the date described in paragraph (1), the Secretary shall submit a final report to the Congress that includes, in an appendix, any findings by the Institute of Medicine concerning research on the strategies discussed in the draft report and any modifications made by the Secretary based on such findings.

"SEC. 923. NATIONAL PATIENT SAFETY DATABASE.

"(a) AUTHORITY.—

"(1) IN GENERAL.—In conducting activities under this part, the Secretary shall provide for the establishment and maintenance of a database to receive relevant nonidentifiable patient safety work product, and may designate entities to collect relevant nonidentifiable patient safety work product that is voluntarily reported by patient safety organizations upon the request of the Secretary. Any database established or designated under this paragraph may be referred to as a 'National Patient Safety Database'.

"(2) USE OF INFORMATION.—Information reported to any National Patient Safety Database shall be used to analyze national and regional statistics, including trends and patterns of health care errors. The information resulting from such analyses may be included in the annual quality reports prepared under section 913(b)(2).

"(3) ADVISORY ROLE.—The Secretary shall provide scientific support to patient safety organizations, including the dissemination of methodologies and evidence-based information related to root causes and quality improvement.

"(b) STANDARDS.—In establishing or designating a database under subsection (a)(1), the Secretary shall, in consultation with representatives of patient safety organizations, the provider community, and the health information technology industry, determine common formats for the voluntary reporting of nonidentifiable patient safety work product, including necessary elements, common and consistent definitions, and a standardized computer interface for the processing of the work product. To the extent practicable, such standards shall be consistent with the administrative simplification provisions of part C of title XI of the Social Security Act.

"(c) CERTAIN METHODOLOGIES FOR COLLECTION.—The Secretary shall ensure that the methodologies for the collection of nonidentifiable patient safety work product for any National Patient Safety Database include the methodologies developed or recommended by the Patient Safety Task Force of the Department of Health and Human Services.

"(d) FACILITATION OF INFORMATION EXCHANGE.—To the extent practicable, the Secretary may facilitate the direct link of information between providers and patient safety

organizations and between patient safety organizations and any National Patient Safety Database.

“(e) RESTRICTION ON TRANSFER.—Only non-identifiable information may be transferred to any National Patient Safety Database.

“SEC. 924. TECHNICAL ASSISTANCE.

“(a) IN GENERAL.—The Secretary, acting through the Director, may—

“(1) provide technical assistance to patient safety organizations, and to States with reporting systems for health care errors; and

“(2) provide guidance on the type of data to be voluntarily submitted to any National Patient Safety Database.

“(b) ANNUAL MEETINGS.—Assistance provided under subsection (a) may include annual meetings for patient safety organizations to discuss methodology, communication, information collection, or privacy concerns.

“SEC. 925. CERTIFICATION OF PATIENT SAFETY ORGANIZATIONS.

“(a) IN GENERAL.—Not later than 6 months after the date of enactment of the Patient Safety and Quality Improvement Act, the Secretary shall establish a process for certifying patient safety organizations.

“(b) PROCESS.—The process established under subsection (a) shall include the following:

“(1) Certification of patient safety organizations by the Secretary or by such other national or State governmental organizations as the Secretary determines appropriate.

“(2) If the Secretary allows other governmental organizations to certify patient safety organizations under paragraph (1), the Secretary shall establish a process for approving such organizations. Any such approved organization shall conduct certifications and reviews in accordance with this section.

“(3) A review of each certification under paragraph (1) (including a review of compliance with each criterion in this section and any related implementing standards as determined by the Secretary through rule-making) not less often than every 3 years, as determined by the Secretary.

“(4) Revocation of any such certification by the Secretary or other such governmental organization that issued the certification, upon a showing of cause.

“(c) CRITERIA.—A patient safety organization must meet the following criteria as conditions of certification:

“(1) The mission of the patient safety organization is to conduct activities that are to improve patient safety and the quality of health care delivery and is not in conflict of interest with the providers that contract with the patient safety organization.

“(2) The patient safety organization has appropriately qualified staff, including licensed or certified medical professionals.

“(3) The patient safety organization, within any 2 year period, contracts with more than 1 provider for the purpose of receiving and reviewing patient safety work product.

“(4) The patient safety organization is not a component of a health insurer or other entity that offers a group health plan or health insurance coverage.

“(5) The patient safety organization is managed, controlled, and operated independently from any provider that contracts with the patient safety organization for reporting patient safety work product.

“(6) To the extent practical and appropriate, the patient safety organization collects patient safety work product from providers in a standardized manner that permits valid comparisons of similar cases among similar providers.

“(d) ADDITIONAL CRITERIA FOR COMPONENT ORGANIZATIONS.—If a patient safety organi-

zation is a component of another organization, the patient safety organization must, in addition to meeting the criteria described in subsection (c), meet the following criteria as conditions of certification:

“(1) The patient safety organization maintains patient safety work product separately from the rest of the organization, and establishes appropriate security measures to maintain the confidentiality of the patient safety work product.

“(2) The patient safety organization does not make an unauthorized disclosure under this Act of patient safety work product to the rest of the organization in breach of confidentiality.

“(3) The mission of the patient safety organization does not create a conflict of interest with the rest of the organization.”.

(b) AUTHORIZATION OF APPROPRIATIONS.—Section 937 of the Public Health Service Act (as redesignated by subsection (a)) is amended by adding at the end the following:

“(e) PATIENT SAFETY AND QUALITY IMPROVEMENT.—For the purpose of carrying out part C, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2004 through 2008.”.

SEC. 102. PROMOTING THE DIFFUSION AND INTEROPERABILITY OF INFORMATION TECHNOLOGY SYSTEMS INVOLVED WITH HEALTH CARE DELIVERY.

(a) VOLUNTARY STANDARDS.—

(1) IN GENERAL.—Not later than 18 months after the date of the enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the “Secretary”) shall—

(A) develop or adopt voluntary national standards that promote the interoperability of information technology systems involved with health care delivery, including but not limited to computerized physician order entry;

(B) in developing or adopting such standards, take into account—

(i) the ability of such systems to capture and aggregate clinically specific data to enable evidence-based medicine and other applications that promote the electronic exchange of patient medical record information; and

(ii) the cost that meeting such standards would have on providing health care in the United States and the increased efficiencies in providing such care achieved under the standards;

(C) in developing or adopting such standards and to the extent practicable, test the efficacy, usability, and scalability of proposed interoperability standards within a variety of clinical settings, including an urban academic medical center, a rural hospital, a community health center, and a community hospital; and

(D) submit a report to the Congress containing recommendations on such standards.

(2) CONSULTATION.—In developing or adopting standards under paragraph (1)(A), the Secretary shall consider the recommendations of the National Committee on Vital Health Statistics for the standardization of message formatting, coding, and vocabulary for interoperability of information technology systems involved with health care delivery. The Secretary shall consult with representatives of the health information technology industry and the provider community who are involved with the development of interoperability standards.

(b) UPDATES.—The Secretary shall provide for the ongoing review and periodic updating of the standards developed under subsection (a).

SEC. 103. REQUIRED USE OF PRODUCT IDENTIFICATION TECHNOLOGY.

The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) is amended—

(1) in section 502, by adding at the end the following:

“(w) If it is a drug or biological product, unless it includes a unique product identifier for the drug or biological product as required by regulations under section 510(q).”; and

(2) in section 510, by adding at the end the following:

“(q)(1) The Secretary shall issue, and may periodically revise, regulations requiring the manufacturer of any drug or biological product that is subject to regulation by the Food and Drug Administration, or the packager or labeler of a drug or biological product that is subject to regulation by the Food and Drug Administration, to include a unique product identifier on the packaging of the drug or biological product.

“(2) For purposes of this subsection, the term ‘unique product identifier’ means an identification that—

“(A) is affixed by the manufacturer, labeler, or packager to each drug or biological product described in paragraph (1) at each packaging level;

“(B) uniquely identifies the item and meets the standards required by this section; and

“(C) can be read by a scanning device or other technology acceptable to the Secretary.

“(3) A unique product identifier required by regulations issued or revised under paragraph (1) shall be based on—

“(A) the National Drug Code maintained by the Food and Drug Administration;

“(B) commercially accepted standards established by organizations that are accredited by the American National Standards Institute, such as the Health Industry Business Communication Council or the Uniform Code Council; or

“(C) other identification formats that the Secretary deems appropriate.

“(4) The Secretary may, at the Secretary’s discretion, waive the requirements of this section, or add additional provisions that are necessary to safeguard the public health.”.

SEC. 104. GRANTS FOR ELECTRONIC PRESCRIPTION PROGRAMS.

(a) GRANTS.—

(1) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the “Secretary”) may make grants to qualified practitioners for the purpose of establishing electronic prescription programs.

(2) MATCHING FUNDS.—

(A) IN GENERAL.—With respect to the costs of establishing an electronic prescription program, a condition for the receipt of a grant under paragraph (1) is that the qualified practitioner involved agree to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than 50 percent of such costs.

(B) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions required in subparagraph (A) may be in cash or in kind, fairly evaluated, including equipment or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(b) STUDY.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Agency for Healthcare Research and Quality, shall support a study to assess existing scientific evidence regarding the effectiveness and cost-effectiveness of the use of electronic prescription programs intended to improve the efficiency of prescription ordering and the safe and effective use of prescription drugs. The study shall address the following:

(A) The ability of such programs to reduce medical errors and improve the quality and safety of patient care.

(B) The impact of the use of such programs on physicians, pharmacists, and patients, including such factors as direct and indirect costs, changes in productivity, and satisfaction.

(C) The effectiveness of strategies for overcoming barriers to the use of electronic prescription programs.

(2) **REPORT.**—The Secretary shall ensure that, not later than 18 months after the date of the enactment of this Act, a report containing the findings of the study under paragraph (1) is submitted to the appropriate committees of the Congress.

(3) **DISSEMINATION OF FINDINGS.**—The Secretary shall disseminate the findings of the study under paragraph (1) to appropriate public and private entities.

(c) **DEVELOPMENT OF MODEL.**—The Secretary, acting through the Director of the Agency for Healthcare Research and Quality, may develop an Internet-based mathematical model that simulates the cost and effectiveness of electronic prescription programs for qualified practitioners. The model may be designed to allow qualified practitioners to estimate, through an interactive interface, the impact of electronic prescribing on their practices, including the reduction in drug-related health care errors.

(d) **DEFINITIONS.**—For purposes of this section:

(1) The term “electronic prescription program”—

(A) means a program for the electronic submission and processing of prescriptions; and

(B) includes the hardware (including computers and other electronic devices) and software programs for the electronic submission of prescriptions to pharmacies, the processing of such submissions by pharmacies, and decision-support programs.

(2) The term “qualified practitioner” means a practitioner licensed by law to administer or dispense prescription drugs.

SEC. 105. GRANTS TO HOSPITALS AND OTHER HEALTH CARE PROVIDERS FOR INFORMATION TECHNOLOGIES.

(a) **IN GENERAL.**—The Secretary of Health and Human Services (in this section referred to as the “Secretary”) shall make grants to hospitals and other health care providers (but not more than 1 grant to any 1 hospital or provider) to pay the costs of acquiring or implementing information technologies whose purposes are—

(1) to improve quality of care and patient safety; and

(2) to reduce adverse events and health care complications resulting from medication errors.

(b) **SPECIAL CONSIDERATION.**—In making grants under subsection (a), the Secretary shall give special consideration to applicants who seek to promote the following:

(1) Interoperability across hospital services or departments using standards developed or adopted by the Secretary under section 102.

(2) Electronic communication of patient data across the spectrum of health care delivery.

(3) Computerized physician order entry or bar coding applications.

(4) Electronic communication of patient data in hospitals that provide services to underserved or low-income populations.

(5) Improved clinical decisionmaking through acquisition and implementation of decision-support technologies.

(c) **CERTAIN GRANT CONDITIONS.**—A condition for the receipt of a grant under subsection (a) is that the applicant involved meet the following requirements:

(1) The applicant agrees to carry out a program to measure, analyze, and report patient

safety and medical errors at the hospital or other health care provider involved, to submit to the Secretary a description of the methodology that will be used, and to have such program in effect as soon as practicable after the application for the grant is approved, without regard to whether information technologies under the grant have been implemented.

(2) The applicant has arranged for an evaluation that addresses the effectiveness and cost-effectiveness of the information technology for which the grant is provided and its impact on the quality and safety of patient care, submitted the evaluation plan to the Secretary, and received approval from the Secretary of the applicant’s methodology.

(3) The applicant has or is developing a patient safety evaluation system (as that term is defined in section 921 of the Public Health Service Act (as amended by section 101)) for reporting health care errors to a patient safety organization.

(4) The applicant agrees to provide the Secretary with such information as the Secretary may require regarding the use of funds under this program or its impact.

(5) The applicant provides assurances satisfactory to the Secretary that any information technology planned, acquired, or implemented with grant funds under this section will be part of an information program that—

(A) carries out the purposes described in subsection (a); and

(B) is comprehensive or will be expanded to become comprehensive, regardless of whether Federal assistance is available for such expansion.

(d) **TECHNICAL ASSISTANCE TO GRANTEEES.**—The Secretary, acting through the Director of the Agency for Healthcare Research and Quality, shall provide technical assistance to applicants and grantees to ensure the appropriate evaluation of the information technologies for which grants are awarded under this section, such as—

(1) reviewing and providing technical assistance on the applicant’s proposed evaluation;

(2) developing mechanisms to ensure ongoing communications between grantees and evaluators to facilitate the identification and resolution of problems as they arise, ensure mutual learning, and promote the rapid dissemination of information;

(3) reviewing the interim and final reports required under subsection (e); and

(4) disseminating evidence-based information in interim and final reports to patient safety organizations, as appropriate.

(e) **EVALUATION REPORTS BY GRANTEE.**—A condition for the receipt of a grant under subsection (a) is that the applicant agree to submit an interim and a final report to the Secretary in accordance with this subsection.

(1) **INTERIM REPORT.**—Not later than 1 year after the implementation of information technologies under the grant is completed, the applicant will submit an interim report to the Secretary describing the initial effectiveness of such technologies in carrying out the purposes described in subsection (a).

(2) **FINAL REPORT.**—Not later than 3 years after the implementation of information technologies under the grant is completed, the applicant will submit a final report to the Secretary describing the effectiveness and cost-effectiveness of such technologies and addressing other issues determined to be important in carrying out the purposes described in subsection (a).

(3) **RELATION TO DISBURSEMENT OF GRANT.**—In disbursing a grant under subsection (a), the Secretary shall withhold $\frac{1}{3}$ of the grant

until the grantee submits to the Secretary the report required in paragraph (1).

(f) **REPORTS BY SECRETARY.**—

(1) **INTERIM REPORTS.**—

(A) **IN GENERAL.**—Through the fiscal year preceding the fiscal year in which the final report under paragraph (2) is prepared, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate periodic reports on the grant program under subsection (a). Such reports shall be submitted not less frequently than once each fiscal year, beginning with fiscal year 2004.

(B) **CONTENTS.**—A report under subparagraph (A) shall include information on—

(i) the number of grants made;

(ii) the nature of the projects for which funding is provided under the grant program;

(iii) the geographic distribution of grant recipients; and

(iv) such other matters as the Secretary determines appropriate.

(2) **FINAL REPORT.**—Not later than 180 days after the date on which the last of the reports is due under subsection (e)(2), the Secretary shall submit a final report to the committees referred to in paragraph (1)(A) on the grant program under subsection (a), together with such recommendations for legislation and administrative action as the Secretary determines appropriate.

(g) **DEFINITIONS.**—For purposes of this section:

(1) The term “costs”, with respect to information technologies referred to in subsection (a), includes total expenditures incurred for—

(A) purchasing, leasing, and installing computer software and hardware, including hand-held computer technologies;

(B) making improvements to existing computer software and hardware; and

(C) purchasing or leasing communications capabilities necessary for clinical data access, storage, and exchange.

(2) The term “health care provider” has the same meaning given to the term “provider” in section 921 of the Public Health Services Act (as amended by this Act).

(h) **TERMINATION OF GRANT AUTHORITIES.**—The authority of the Secretary to make grants under subsection (a) terminates upon the expiration of fiscal year 2011.

(i) **MATCHING FUNDS.**—

(1) **IN GENERAL.**—With respect to the costs of a grant to be carried out under this section, such grant may be made only if the applicant agrees to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than 50 percent of such costs (\$1 for each \$1 of Federal funds provided in the grant).

(2) **DETERMINATION OF AMOUNTS CONTRIBUTED.**—Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

SEC. 106. AUTHORIZATION OF APPROPRIATIONS FOR GRANTS UNDER SECTIONS 104 AND 105.

For the purpose of carrying out sections 104 and 105, there are authorized to be appropriated \$25,000,000 for each of fiscal years 2004 and 2005.

TITLE II—MEDICAL INFORMATION TECHNOLOGY ADVISORY BOARD.

SEC. 201. MEDICAL INFORMATION TECHNOLOGY ADVISORY BOARD.

Title XI of the Social Security Act is amended by adding at the end the following new section:

"MEDICAL INFORMATION TECHNOLOGY ADVISORY BOARD

"SEC. 1180. (a) ESTABLISHMENT.—

"(1) IN GENERAL.—Not later than 3 months after the date of the enactment of this section, the Secretary shall appoint an advisory board to be known as the 'Medical Information Technology Advisory Board' (in this section referred to as the 'MITAB').

"(2) CHAIRMAN.—The Secretary shall designate one member as chairman. The chairman shall be an individual affiliated with an organization having expertise creating American National Standards Institute (ANSI) accepted standards in health care information technology and a member of the National Committee for Vital and Health Statistics.

"(b) COMPOSITION.—

"(1) IN GENERAL.—The MITAB shall consist of not more than 17 members that include—

"(A) experts from the fields of medical information, information technology, medical continuous quality improvement, medical records security and privacy, individual and institutional health care clinical providers, health researchers, and health care purchasers;

"(B) one or more staff experts from each of the following: the Centers for Medicare & Medicaid Services, the Agency for Healthcare Research and Quality, and the Institute of Medicine of the National Academy of Sciences;

"(C) representatives of private organizations with expertise in medical informatics;

"(D) a representative of a teaching hospital; and

"(E) one or more representatives of the health care information technology industry.

"(2) TERMS OF APPOINTMENT.—The term of any appointment under paragraph (1) to the MITAB shall be for the life of the MITAB.

"(3) MEETINGS.—The MITAB shall meet at the call of its chairman or a majority of its members.

"(4) VACANCIES.—A vacancy on the MITAB shall be filled in the same manner in which the original appointment was made not later than 30 days after the MITAB is given notice of the vacancy and shall not affect the power of the remaining members to execute the duties of the MITAB.

"(5) COMPENSATION.—Members of the MITAB shall receive no additional pay, allowances, or benefits by reason of their service on the MITAB.

"(6) EXPENSES.—Each member of the MITAB shall receive travel expenses and per diem in lieu of subsistence in accordance with sections 5702 and 5703 of title 5, United States Code.

"(c) DUTIES.—

"(1) IN GENERAL.—The MITAB shall on an ongoing basis advise, and make recommendations to, the Secretary regarding medical information technology, including the following:

"(A) The best current practices in medical information technology.

"(B) Methods for the adoption (not later than 2 years after the date of the enactment of this section) of a uniform health care information system interface between and among old and new computer systems.

"(C) Recommendations for health care vocabulary, messaging, and other technology standards (including a common lexicon for computer technology) necessary to achieve the interoperability of health care information systems for the purposes described in subparagraph (E).

"(D) Methods of implementing—

"(i) health care information technology interoperability standardization; and

"(ii) records security.

"(E) Methods to promote information exchange among health care providers so that long-term compatibility among information systems is maximized, in order to do one or more of the following:

"(i) To maximize positive outcomes in clinical care—

"(I) by providing decision support for diagnosis and care; and

"(II) by assisting in the emergency treatment of a patient presenting at a facility where there is no medical record for the patient.

"(ii) To contribute to (and be consistent with) the development of the patient assessment instrument provided for under section 545 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, and to assist in minimizing the need for new and different records as patients move from provider to provider.

"(iii) To reduce or eliminate the need for redundant records, paperwork, and the repetitive taking of patient histories and administering of tests.

"(iv) To minimize medical errors, such as administration of contraindicated drugs.

"(v) To provide a compatible information technology architecture that facilitates future quality and cost-saving needs and that avoids the financing and development of information technology systems that are not readily compatible.

"(2) REPORTS.—

"(A) INITIAL REPORT.—No later than 18 months after the date of the enactment of this section, the MITAB shall submit to Congress and the Secretary an initial report concerning the matters described in paragraph (1). The report shall include—

"(i) the practices described in paragraph (1)(A), including the status of health care information technology standards being developed by private sector and public-private groups;

"(ii) recommendations for accelerating the development of common health care terminology standards;

"(iii) recommendations for completing development of health care information system messaging standards; and

"(iv) progress toward meeting the deadline described in paragraph (1)(B) for adoption of methods described in such paragraph.

"(B) SUBSEQUENT REPORTS.—During each of the 2 years after the year in which the report is submitted under subparagraph (A), the MITAB shall submit to Congress and the Secretary an annual report relating to additional recommendations, best practices, results of information technology improvements, analyses of private sector efforts to implement the interoperability standards established in section 102 of the Patient Safety and Quality Improvement Act, and such other matters as may help ensure the most rapid dissemination of best practices in health care information technology.

"(d) STAFF AND SUPPORT SERVICES.—

"(1) EXECUTIVE DIRECTOR.—

"(A) APPOINTMENT.—The Chairman shall appoint an executive director of the MITAB.

"(B) COMPENSATION.—The executive director shall be paid the rate of basic pay for level V of the Executive Schedule.

"(2) STAFF.—With the approval of the MITAB, the executive director may appoint such personnel as the executive director considers appropriate.

"(3) APPLICABILITY OF CIVIL SERVICE LAWS.—The staff of the MITAB shall be appointed without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title (relating to classification and General Schedule pay rates).

"(4) EXPERTS AND CONSULTANTS.—With the approval of the MITAB, the executive director may procure temporary and intermittent services under section 3109(b) of title 5, United States Code.

"(e) POWERS.—

"(1) HEARINGS AND OTHER ACTIVITIES.—For the purpose of carrying out its duties, the MITAB may hold such hearings and undertake such other activities as the MITAB determines to be necessary to carry out its duties.

"(2) DETAIL OF FEDERAL EMPLOYEES.—Upon the request of the MITAB, the head of any Federal agency is authorized to detail, without reimbursement, any of the personnel of such agency to the MITAB to assist the MITAB in carrying out its duties. Any such detail shall not interrupt or otherwise affect the civil service status or privileges of the Federal employee.

"(3) TECHNICAL ASSISTANCE.—Upon the request of the MITAB, the head of a Federal agency shall provide such technical assistance to the MITAB as the MITAB determines to be necessary to carry out its duties.

"(4) OBTAINING INFORMATION.—The MITAB may secure directly from any Federal agency information necessary to enable it to carry out its duties, if the information may be disclosed under section 552 of title 5, United States Code. Upon request of the Chairman of the MITAB, the head of such agency shall furnish such information to the MITAB.

"(f) TERMINATION.—The MITAB shall terminate 30 days after the date of submission of its final report under subsection (c)(2)(B).

"(g) APPLICABILITY OF FACA.—The provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall apply to the MITAB.

"(h) FUNDING.—There are authorized to be appropriated such sums as are necessary for each fiscal year to carry out this section."

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Florida (Mr. BILIRAKIS) and the gentleman from Louisiana (Mr. JOHN) each will control 20 minutes.

The Chair recognizes the gentleman from Florida (Mr. BILIRAKIS).

GENERAL LEAVE

Mr. BILIRAKIS. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks and to insert extraneous material on H.R. 663, the legislation under consideration.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Florida?

There was no objection.

Mr. BILIRAKIS. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I first commend the leadership of the gentleman from Louisiana (Mr. TAUZIN), chairman of the Committee on Energy and Commerce, and the gentleman from Ohio (Mr. BROWN) and the gentleman from Michigan (Mr. DINGELL), minority leaders on that committee, and the gentleman from California (Mr. THOMAS), chairman of the Committee on Ways and Means, and the gentlewoman from Connecticut (Mrs. JOHNSON), the subcommittee chairman of the Committee on Ways and Means, in helping us bring forward this important bipartisan legislation.

Mr. Speaker, I rise in strong support of the bill. This is a critically important bill which we refer to as the Patient Safety and Quality Improvement Act, and I look forward to its favorable consideration by the House today.

I know most Members are well acquainted with the disturbing frequency and devastating impact of medical errors. Unfortunately, recent events have once again attached a human face to the horrible reality that, sometimes, even the best health care professionals make mistakes.

The work of the Institute of Medicine in this area helped increase the public's focus on this problem, as well as potential solutions. One of the many recommendations that the IOM made in its 1999 report, which they called "To Err Is Human," was that Congress should enact laws to protect the confidentiality of information collected as part of a voluntary medical error reporting system. That IOM recommendation represents the foundation of the Patient Safety and Quality Improvement Act.

Specifically, H.R. 663 defines a new voluntary medical error reporting system whereby the Secretary of Health and Human Services will certify a number of private and public organizations to act as patient safety organizations, PSOs. These patient safety organizations will analyze data on medical errors, determine their causes, and develop and disseminate evidence-based information to providers to help them implement changes that will improve patient safety. H.R. 663 provides peer review protections to the documents and communications providers will submit to patient safety organizations, which we hope will encourage the exchange of this important information.

Mr. Speaker, I believe the bill will help us move from a "culture of blame" to a "culture of safety" and ultimately increase patient safety. The Patient Safety and Quality Improvement Act is the product of excellent, bipartisan work. I urge Members to join me in supporting it today.

Mr. Speaker, I reserve the balance of my time.

Mr. JOHN. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise in support of H.R. 663, the Patient Safety and Quality Improvement Act. This bill is a product of bipartisan negotiations between not only the Committee on Energy and Commerce but also includes key members from both sides of the aisle on the Committee on Ways and Means; and I thank Members on both sides of the aisle for their very hard work on this important piece of legislation.

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It has been more than 3 years since the Institute of Medicine released the landmark study, "To Err Is Human." The Institute of Medicine stated that our health care system is plagued with an epidemic of medical errors. However, many of these mistakes could be

prevented in the health care delivery system and the way that it is delivered.

With this bill, Congress is taking an important step towards reducing medical errors. The Patient Safety and Quality Improvement Act creates a voluntary reporting system that will enable providers to learn from past mistakes. Providers could report information about medical errors to patient safety organizations who would analyze the data in confidence and recommend strategies to prevent future errors. These organizations could share knowledge with each other and with the Agency for Health Care Research and Quality so that all actors in the health care system could benefit.

Congress intends for providers to take these lessons learned and modify their operations to keep their patients safer. This bill requires the Secretary of Health and Human Services to recommend which strategies for reducing medical errors would be appropriate standards for providers in Federal health care programs. No bill can prevent all medical errors, but it is our hope that this legislation will result in real differences that patients can see.

Mr. Speaker, I reserve the balance of my time.

Mr. BILIRAKIS. Mr. Speaker, I yield such time as he may consume to the gentleman from Louisiana (Mr. TAUZIN), the chairman of the full committee, who is more responsible for this piece of legislation than any of us.

Mr. TAUZIN. Mr. Speaker, actually I rise first to commend a Member of the House who has done some extraordinary work, not even on our committee but on the Committee on Ways and Means, and that is the gentleman from Connecticut (Mrs. JOHNSON), who has really contributed mightily to the understanding of this issue and has helped indeed frame much of the solutions that this bill contains. I want to thank the gentleman from Connecticut (Mrs. JOHNSON) and the gentleman from California (Mr. THOMAS) of the Committee on Ways and Means for that vital process. I particularly also want to thank the gentleman from Florida (Mr. BILIRAKIS), the chairman of the Subcommittee on Health, and the gentleman from Ohio (Mr. BROWN) and the gentleman from Michigan (Mr. DINGELL), the ranking members of the subcommittee and the full committee, indeed for the fact that this is a bipartisan effort to do something about medical errors which end up creating victims of a health care system who should never have to suffer because of those errors.

We are told in the project of 1999 that was done by the Institute of Medicine, in that report entitled "To Err Is Human," that as many as 98,000 people in this country die as a result of medical errors. In fact, the news contains the story today of perhaps some errors in a young child who received an organ transplant just this week again. Those

awful stories should come to an end. The first and most important way of ending medical error damage and death in our health care system is in fact to do what we are doing today, and that is to set up a system whereby health care officials and doctors and nurses, clinics and hospitals, can share information. One can learn from the other.

The impediments to sharing information today are many. The ability of a doctor to share information about something that went wrong or a hospital to share information with another hospital about something that could go right in the case of a medical error prevented, those inabilities are corrected in this act. The act creates not only the incentive for information sharing but grants an assistance for the technologies that are going to improve the transfer of information that will make less error in the health care system a reality and, therefore, again save human lives and human misery.

This act will not only improve the quality of our health care system, it will immeasurably improve the safety of the health care facilities and the safety net that surrounds someone who goes into one of those facilities expecting to be healed rather than to come out with an infection.

As the chairman of the Subcommittee on Health said, the effort here is to create a culture of safety by providing a legal protection framework for the information that is reported, that is provided, about quality improvement and patient safety. The thrust is to provide the opportunity for health care providers to submit information to a patient safety organization and have an analysis done so that we can learn from all the information coming in, what works, what does not work, what errors are occurring and why they are occurring, and then to have these same organizations have the benefit of that information in preventing those errors and in improving the safety of their procedures.

There are several provisions aimed at improving the diffusion and functioning of important information technologies that help prevent medical errors. This legislation is not the only one we will work on to help improve patient safety and quality. There are other efforts being undertaken in the States and in the local medical communities of all of our homes. We want to support those efforts as well and will continue to work in a bipartisan fashion as we have done here to help improve the outcomes in our health care system.

In short, today we begin a very aggressive campaign to root out errors within the health care delivery system and to save lives and injury that result from those errors. Tomorrow we will take up the liability questions, the questions of how liability and malpractice cases are pursued in this country. But today we focus on this set of victims as our committee continues to put patients first, as we try to focus all

our health care policy and decision-making on how we can better help patients receive good, quality, safe health care when they go to a health care facility in this country or they seek the services of a health care provider.

This is extremely important stuff we do today. I hope this House understands that while this is a bipartisan effort, while it passed committee on a voice vote, while we are all very supportive of it and very grateful for the work of not only the members of our committee but other committees who have assisted us, I want everyone to know that this is really serious stuff. If this works, we could save nearly 100,000 American citizens who die yearly from these errors. This is important stuff. I urge the House to agree with this important legislation.

Mr. BILIRAKIS. Mr. Speaker, I yield such time as she may consume to the gentlewoman from New York (Mrs. KELLY).

Mrs. KELLY. Mr. Speaker, I rise today in strong support of the Patient Safety and Quality Improvement Act, legislation which will strengthen our health care system and improve patient care. Today we are considering a bill that creates a structured process for reporting errors made during the course of medical treatment. Voluntary and confidential disclosure can help reduce injuries and death due to medical errors. What we have here is the creation of patient safety organizations that are created to conduct comprehensive analyses of what went wrong following a medical mistake. The people who provide health care are given feedback that way so that they can make changes and prevent future occurrences. Compiling this information in a central database will allow providers nationwide to benefit from lessons learned.

The simple message is that we need to learn from our mistakes. For this legislation to be effective, it is essential that practitioners feel comfortable in coming forward with information. I met with a group of doctors and providers in my district and they suggested strongly that we encourage some kind of indemnification so that they could report accurate figures. I am glad to report that this bill contains strong legal protections and provisions to ensure that information reported is treated as confidential, such as whistleblower-type protections. I think that is a very good piece in this bill. Creating a culture of safety surrounding the reporting of medical errors will encourage health care practitioners to report these mistakes.

The Institute of Medicine reported in 1999 that medical errors are the eighth leading cause of death among Americans. I believe this bill will go a long way toward preventing many of these tragic deaths and injuries. Mr. Speaker, the bill makes great sense for patients and for health care providers. I applaud the committee for putting this bill forward, and I urge my colleagues to support this legislation.

Mr. STARK. Mr. Speaker, reducing medical errors is an important goal, and this legislation takes a small step in that direction. But don't be fooled by the rhetoric.

While the legislation offers a glimmer of hope that action will be taken, it does nothing to actually prevent any future medical errors or improve patient safety.

Unfortunately, the timing of the consideration of this bill is driven by crass political motives to provide cover for the anti-patient legislation that will be considered tomorrow.

I personally think one of our goals should be to first do no harm, and I believe this bill accomplishes that. But it doesn't do much good either.

Federal agencies, states, and the private sector are making strides in this area. But there are certain things that only Congress can do. The legislation before us is not the best example of what that role should be.

This legislation reflects a tenuously and delicately crafted compromise that assures that information which is discoverable today will remain discoverable if this bill becomes law. While the bill creates a new federal privilege for the data created for this new voluntary reporting system, it does not erode a patient's right to access information that is currently available and would be available but for this new system. I am satisfied that—as currently written—it seems to accomplish that goal. But I am concerned about how it will be used and intend to keep an eye on it.

The bill establishes a voluntary system under which patient safety organizations may be created, providers may report their mistakes and the Secretary may act to improve patient safety practices.

But let's talk about what this bill does not do.

It does not reflect the Institute of Medicine's recommendations from the landmark 1999 report.

It does not ensure that providers change their practices to prevent medical errors, based on the insight that might be gained from the system created under this bill.

It does not require a rigorous evaluation of this new voluntary system, which may be ineffective.

The IOM report estimated that as many as 98,000 hospital deaths each year may be attributable to preventable medical errors, yet this legislation fails to assure any reduction in this tragic statistic. It certainly doesn't address the recent organ transplant tragedies.

There are a number of steps that can be taken today to reduce errors and improve patient safety, but too few providers have implemented these policies.

For example, only one percent of hospitals require use of computerized order-entry systems to reduce pharmaceutical prescribing, dispensing and administration errors.

Similarly, last year the American Nurses Association testified that a significant portion of hospital errors are the result of fatigued and overworked staff. Around the country, nurses are regularly forced to work more hours than are believed to be safe to provide quality care. I introduced legislation (H.R. 745) to prohibit this unsafe practice.

Without assurances that the system will use this newly protected data to improve practice, this lop-sided exercise benefits the providers at the expense of patients, and the trade-off may not be worth it.

Finally, let's not forget that the timing of this legislation is not accidental. This legislation is being brought up today in an effort to distract from the anti-patient legislation that Congress will take up tomorrow. Don't be fooled by the rhetoric.

I intend to vote for this bill because it does no harm and lays the groundwork for future action. But we have missed an opportunity to do more.

Mr. DINGELL. Mr. Speaker, I rise in support of H.R. 663, the "Patient Safety and Quality Improvement Act." This bipartisan bill is the product of collaboration with my colleagues on the Committee on Energy and Commerce, particularly Chairmen TAUZIN and BILIRAKIS, and Subcommittee Ranking Member BROWN. I also note that this legislation builds on the work of my colleagues on the Committee on Ways and Means, including Representatives JOHNSON, STARK, THOMAS, and RANGEL. I thank all who have made important contributions to this bill.

The Patient Safety and Quality Improvement Act addresses a problem that many of us are familiar with. According to a December 2003 survey by the Harvard School of Public Health and the Kaiser Family Foundation, 42 percent of the public says that they or a family member have experienced a medical error.

This bill contains one piece of the puzzle that must be completed in order to reduce medical errors. It would create a voluntary reporting system for the purpose of learning from medical mistakes.

Under this voluntary reporting system, health care providers could report information on medical errors to Patient Safety Organizations. These organizations would help providers analyze what went wrong and identify what strategies could prevent future mistakes. It is our intent that providers would take this knowledge and make changes in the health care delivery system to improve care for patients.

I also hope that the Secretary of Health and Human Services would use this knowledge to set some basic guidelines that all providers would be required to follow. Patients should be able to expect that providers are adhering to certain safety standards before they seek treatment from a doctor, hospital, or other facility.

The best patient safety bill, however, cannot prevent all medical errors. Unfortunately, there will be cases where a medical mistake is made and a patient suffers injury or death as a result. If medical malpractice was involved in these cases, patients and their families should be entitled to seek compensation under a fair and accessible legal system. It would be disingenuous to suggest that the limited legislation before us today could supplant the vital role of legal remedies for medical malpractice.

Again, I thank my colleagues for their cooperation in writing this patient safety bill, and I look forward to seeing the improvements that will result when it is implemented.

Mr. ENGEL. Mr. Speaker, HR 663, the Patient Safety and Quality Improvement Act, is important legislation that holds great promise to reduce medical errors. This legislation will allow medical errors to be reported so we can learn from mistakes and hopefully prevent future errors from occurring. By allowing errors or near misses to be reported anonymously it takes away the fear many providers have in regards to reporting errors.

I am particularly pleased that the legislation creates the Medical Information Technology Assessment Board which will work in conjunction with the Department of Health and Human Services to develop national interoperability standards. I was pleased to work with the Committee to get this provision included in the bill. These national standards will allow all aspects of health care technology to become compatible. Thus, computers, hand held electronic charts and other new devices that hold a variety of medical information, including laboratory and radiology results, pharmacy orders, etc., will all be compatible. This compatibility will greatly reduce medical errors. Further, the legislation authorizes grants to test the interoperability standards. This is vitally important as it will prove the efficacy, usability, and scalability of interoperability standards, thus encouraging hospitals and other health care facilities and providers to adopt the standards and invest in medical informatics.

Mr. Speaker, I am proud to be a cosponsor of the Patient Safety and Quality Improvement Act, and I thank both the Energy and Commerce and Ways and Means Committees for working in a bipartisan fashion to produce good legislation on such an important issue.

Mr. GREEN of Texas. Mr. Speaker, I am pleased to rise in support of the Patient Safety and Quality Improvement Act. This important legislation takes a number of steps to reduce medical errors.

In November of 1999, the Institute of Medicine released its groundbreaking report, *To Err is Human*, which raises serious concerns about shortcomings in the area of patient safety.

According to some estimates, as many as 98,000 people die in any given year from medical errors that occur in hospitals. That's more than die from motor vehicle accidents, breast cancer, or AIDS.

The costs of preventable adverse events are staggering. The direct and indirect costs of medical errors range from \$17 billion to \$29 billion. By any standard, that is far too much.

The Institute of Medicine recommended a number of options to help reduce medical errors, such as the creation of a Center for Patient Safety within the Agency for Health Quality and Research.

They also suggested a new system of reporting, and better use of technological advancements.

The legislation we are considering today incorporates many of the suggestions made by IOM, and will go a long way to help health care providers improve patient safety and prevent medical errors.

This legislation creates a "culture of safety" by encouraging providers to report medical mistakes. By reporting these problems, physicians and other providers are able to learn from their mistakes and prevent them from happening in the future.

This legislation also permits the Secretary of the Department of Health and Human Services to provide to patient safety organizations and to States technical assistance with reporting systems for health care errors, to es-

tablish a process to certify patient safety organizations, and to develop or adopt voluntary national standards promoting the interoperability of information technology systems involved with health care delivery.

These provisions will go a long way in helping our hospitals and physicians offices a safer place. I urge my colleagues to support this legislation and hope to see it signed by the President this year.

Mr. JOHN. Mr. Speaker, I yield back the balance of my time.

Mr. BILIRAKIS. Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore (Mr. LAHOOD). The question is on the motion offered by the gentleman from Florida (Mr. BILIRAKIS) that the House suspend the rules and pass the bill, H.R. 663, as amended.

The question was taken.

The SPEAKER pro tempore. In the opinion of the Chair, two-thirds of those present have voted in the affirmative.

Mr. BILIRAKIS. Mr. Speaker, on that I demand the yeas and nays.

The yeas and nays were ordered.

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX and the Chair's prior announcement, further proceedings on this motion will be postponed.

ANNOUNCEMENT BY THE SPEAKER PRO TEMPORE

The SPEAKER pro tempore. Pursuant to clause 8 of rule XX, proceedings will now resume on two of the motions to suspend the rules previously postponed.

Votes will be taken in the following order:

H.R. 659, by the yeas and nays;

H.R. 389, by the yeas and nays.

Pursuant to House Resolution 67, the official photograph will be taken between these two votes, each of which will be conducted as a 15-minute vote.

HOSPITAL MORTGAGE INSURANCE ACT OF 2003

The SPEAKER pro tempore. The pending business is the question of suspending the rules and passing the bill, H.R. 659, as amended.

The Clerk read the title of the bill.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from California (Mr. GARY G. MILLER) that the House suspend the rules and pass the bill, H.R. 659, on which the yeas and nays are ordered.

The vote was taken by electronic device, and there were—yeas 419, nays 0, not voting 15, as follows:

[Roll No. 56]

YEAS—419

Abercrombie
Ackerman
Aderholt
Akin

Alexander
Allen
Andrews
Baca

Bachus
Baird
Baker
Baldwin

Ballance
Ballenger
Barrett (SC)
Bartlett (MD)
Barton (TX)
Bass
Beauprez
Becerra
Bell
Bereuter
Berkley
Berry
Biggert
Billirakis
Bishop (GA)
Bishop (NY)
Bishop (UT)
Blackburn
Blumenauer
Blunt
Boehlert
Boehner
Bonilla
Bonner
Bono
Boozman
Boswell
Boucher
Boyd
Bradley (NH)
Brady (PA)
Brady (TX)
Brown (OH)
Brown (SC)
Brown, Corrine
Brown-Waite,
 Ginny
Burgess
Burns
Burr
Burton (IN)
Buyer
Calvert
Camp
Cannon
Cantor
Capito
Capps
Capuano
Cardin
Cardoza
Carson (IN)
Carson (OK)
Carter
Case
Castle
Chabot
Chocola
Clay
Clyburn
Coble
Cole
Collins
Conyers
Cooper
Costello
Cox
Cramer
Crane
Crenshaw
Crowley
Cubin
Culberson
Cummings
Cunningham
Davis (AL)
Davis (CA)
Davis (FL)
Davis (IL)
Davis (TN)
Davis, Jo Ann
Davis, Tom
Deal (GA)
DeFazio
DeGette
Delahunt
DeLauro
DeLay
DeMint
Deutsch
Diaz-Balart, L.
Diaz-Balart, M.
Dicks
Dingell
Doggett
Dooley (CA)
Doolittle
Doyle
Dreier

Duncan
Dunn
Edwards
Ehlers
Emanuel
Emerson
Engel
English
Eshoo
Etheridge
Evans
Everett
Farr
Fattah
Feeney
Ferguson
Filner
Flake
Fletcher
Foley
Forbes
Ford
Frank (MA)
Franks (AZ)
Frelinghuysen
Frost
Gallegly
Garrett (NJ)
Gerlach
Gibbons
Gillmor
Gingrey
Gonzalez
Goode
Goodlatte
Gordon
Goss
Granger
Graves
Green (TX)
Green (WI)
Greenwood
Grijalva
Gutierrez
Gutknecht
Hall
Harman
Harris
Hart
Hastings (FL)
Hastings (WA)
Hayes
Hayworth
Hefley
Hensarling
Herger
Hill
Hinchey
Hinojosa
Hobson
Hoekstra
Holden
Holt
Honda
Hoolley (OR)
Hostettler
Houghton
Hoyer
Hulshof
Hunter
Isakson
Israel
Issa
Istook
Jackson (IL)
Jackson-Lee
 (TX)
Janklow
Jefferson
Jenkins
John
Johnson (CT)
Johnson, E. B.
Johnson, Sam
Jones (NC)
Jones (OH)
Kanjorski
Kaptur
Keller
Kelly
Kennedy (MN)
Kennedy (RI)
Kildee
Kilpatrick
Kind
King (IA)
King (NY)
Kingston
Kirk

Klecza
Kline
Knollenberg
Kolbe
Kucinich
LaHood
Lampson
Langevin
Lantos
Larsen (WA)
Larson (CT)
Latham
LaTourette
Leach
Lee
Levin
Lewis (CA)
Lewis (GA)
Lewis (KY)
Linder
Lipinski
LoBiondo
Lofgren
Lowey
Lucas (KY)
Lucas (OK)
Lynch
Majette
Maloney
Manzullo
Markey
Marshall
Matheson
Matsui
McCarthy (MO)
McCarthy (NY)
McCollum
McCotter
McCrery
McDermott
McGovern
McHugh
McInnis
McIntyre
McKeon
McNulty
Meehan
Meek (FL)
Meeks (NY)
Menendez
Mica
Michaud
Millender-
 McDonald
Miller (FL)
Miller (MI)
Miller (NC)
Miller, Gary
Miller, George
Mollohan
Moore
Moran (KS)
Moran (VA)
Murphy
Murtha
Muggrave
Myrick
Nadler
Napolitano
Neal (MA)
Nethercutt
Ney
Northup
Norwood
Nunes
Nussle
Oberstar
Obey
Olver
Ortiz
Osborne
Ose
Otter
Owens
Oxley
Pallone
Pascrell
Pastor
Paul
Payne
Pearce
Pelosi
Pence
Peterson (MN)
Peterson (PA)
Petri
Pickering
Pitts
Platts